K112278

NOV - 4 2011

Ascension Orthopedics

ASCENSION ORTHOPEDICS, INC
8700 CAMERON ROAD
AUSTIN, TEXAS 78754

Summary of Safety and Effectiveness

Sponsor:	Ascension Orthopedics, Inc. 8700 Cameron Road Austin, TX 78754-3832
Contact Person:	Bradley W. Strasser Regulatory Affairs Specialist 512-836-5001 ext. 1541
Date:	05 August 2011
Trade Name:	*Ascension® NuGrip®* CMC Implant
Common Name:	Carpometacarpal (CMC) Implant
Product Code:	KYI – Prosthesis, Wrist, Carpal Trapezium
Classification:	21 CFR §888.3770 – Wrist joint carpal trapezium polymer prosthesis
Panel:	Orthopedic
Predicate Device:	*Ascension® PyroHemiSphere®* (PHS); K041451, cleared 25 August 2004; manufactured by Ascension Orthopedics, Inc. *Ascension® Saddle®* PyroCarbon CMC; K061451, cleared 11 August 2006; manufactured by Ascension Orthopedics, Inc.
Device Description:	The *Ascension NuGrip* CMC Implant is a single-use, uncemented one-piece implant for the basal thumb joint. It is constructed of a graphite core encased in a layer of pyrolytic carbon. The device is offered in 9 different combinations of 3 head and 4 stem sizes. The *NuGrip* represents incremental design modifications to the *Ascension PyroHemiSphere*, including an extended proximal spherical head, a collar at the head base, modified stem geometry, and additional implant sizes.
Intended Use:	The *Ascension NuGrip* CMC Implant is intended to replace the proximal end of the first metacarpal in cases of rheumatoid arthritis, traumatic arthritis,

K112278

	osteoarthritis, or post fracture deformation or bone loss which present as either a painful, unstable thumb or a thumb with limited range of motion.
Basis of Substantial Equivalence:	The *Ascension NuGrip* CMC Implant is manufactured using identical materials and processes as the *Ascension PyroHemiSphere* CMC implant. The design modifications represented in the *NuGrip* do not raise new issues of safety or effectiveness, as shown by performance testing and analysis. The *NuGrip* indications for use and intended function remain unchanged from the predicate *PyroHemiSphere.*
Non-Clinical Performance Data:	In order to support substantial equivalence of the *NuGrip* implants to the predicate devices, the following non-clinical testing and analysis was conducted: • CMC Joint Biomechanics Review • Static Compression-Bending Testing • Basal Thumb Implant Endurance Testing • System Verification Report/Strength Analysis • PyroCarbon Wear Characteristics Analysis
Clinical Performance Data:	No clinical performance data were needed to support substantial equivalence of the design modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV - 4 2011

Ascension Orthopedics, Inc.
% Mr. Bradley W. Strasser
Regulatory Affairs Specialist
8700 Cameron Road
Austin, Texas 78754

Re: K112278
Trade/Device Name: Ascension NuGrip CMC Implant
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist joint carpal trapezium polymer prosthesis
Regulatory Class: II
Product Code: KYI
Dated: August 5, 2011
Received: August 9, 2011

Dear Mr. Strasser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112278

Device Name:

Ascension® NuGrip® CMC Implant

Indications for Use:

The Ascension® NuGrip® CMC Implant is intended to replace the proximal end of the first metacarpal in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis, or post fracture deformation or bone loss which present as either a painful, unstable thumb or a thumb with limited range of motion.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112278